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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of

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Complete if Known	
Application Number	10/052,092
Filing Date	January 18, 2002
First Named Inventor	Suzanne Fuqua
Art Unit	N/A 1634
Examiner Name	Not Yet Assigned Switzer
Attorney Docket Number	HO-P02102US2

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### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
SB	AA	5563035-	10-08-1996	Weigel	
SB	AB	6162606-	12-19-2000	Raam	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

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Sheet	2	of	4	Attorney Docket Number	HO-P02102US2

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.
✓	CA	Burstein, Nelson A.; Overall Principles of Cancer Management - Hormone Therapy; published in Cancer, A Manual for Practitioners (American Cancer Society Massachusetts Division); 6th Edition, 1982, pages 67 - 71
✓	CB	Donegan, William L.; Prognostic Factors; Cancer 1992; 70:1755 - 1764
✓	CC	Brooks, S. C., et al.; Relation of Tumor Content of Estrogen and Progesterone Receptors with Response of Patient to Endocrine Therapy; Cancer 46:2775 - 2778, 1980
✓	CD	Degensheln, George A., et al.; The Value of Progesterone Receptor Assays in the Management of Advanced Breast Cancer; Cancer 46:2789 - 2793, 1980
✓	CE	Fugua, Suzanne A. W., et al.; Variant Human Breast Tumor Estrogen Receptor with Constitutive Transcriptional Activity; Cancer Research 51:105 - 109, January 1, 1991
✓	CF	Gelbfish, Gary A., et al.; Relationship of Estrogen and Progesterone Receptors to Prognosis in Breast Cancer; Ann Surg. 207(1):75 - 79, January 1998
✓	CG	Greene, Geoffrey, et al.; Sequence and Expression of Human Estrogen Receptor Complementary DNA; Science Vol. 231, pages 1150 - 1154; March 7, 1986
✓	CH	Kohail, Hanan M., et al.; A Multifactorial Analysis of Steroid Hormone Receptors in Stages I and II Breast Cancer; Ann. Surg 201(5):611 - 617, May, 1985
✓	CI	Eilidge, Richard M., et al.; Prognostic Factors and Therapeutic Decisions in Axillary Node-Negative Breast Cancer; Annu. Rev. Med. 1993, 44:201 - 210
✓	CJ	McGuire, William L.; Prognostic factors for recurrence and survival in human breast cancer; Breast Cancer Research and Treatment 10:5 - 9, 1987
✓	CK	Millis, Rosemary R.; Correlation of Hormone Receptors with Pathological Features in Human Breast Cancer; Cancer 46:2869 - 2871, 1980
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✓	CM	O'Connell, Peter, et al.; Loss of Heterozygosity at D14S62 and Metastatic Potential of Breast Cancer; REPORTS, Journal of the National Cancer Institute, Vol. 91(16), pages 1391 - 1397; August 18, 1999
✓	CN	Shousha, S., et al.; Oestrogen receptors in mucinous carcinoma of the breast: an immunohistological study using paraffin wax sections; J. Clin. Pathol. 1989; 42:902 - 905
✓	CO	Shousha, S., et al.; Immunohistological study of oestrogen receptors in breast carcinomas that are biochemically receptor negative; J. Clin. Pathol. 1990; 43:239 - 242
✓	CP	Williams, M. R., et al.; Oestrogen receptors in primary and advanced breast cancer: An eight year review of 704 cases; Br. J. Cancer (1987), 55:67 - 73
✓	CQ	Vogelstein, Bert, et al.; The multistep nature of cancer; TIG Vol. 9 (4), pages 138 - 141, April 1993
✓	CR	Weigel, Ronald J., et al.; Transcriptional Control of Estrogen Receptor in Estrogen Receptor-negative Breast Carcinoma; Cancer Research, Vol. 53 (15):3472 - 3474, August 1, 1993
✓	CS	Scott, Gary K., et al.; Truncated Forms of DNA-binding Estrogen Receptors in Human Breast Cancer; J. Clin. Invest. 1991, 88:700 - 706
✓	CT	Ince, B. Avery, et al.; Powerful Dominant Negative Mutants of the Human Estrogen Receptor; The Journal of Biological Chemistry, Vol. 268 (19), 14026 - 14032, 1993
✓	CU	Fuqua, Suzanne A. W., et al.; Inhibition of Estrogen Receptor Action by a Naturally Occurring Variant in Human Breast Tumors; Cancer Research 52:483 - 486, January 15, 1992
✓	CV	Castles, Carl G., et al.; Expression of a Constitutively Active Estrogen Receptor Variant in the Estrogen Receptor-negative BT-20 Human Breast Cancer Cell Line; Cancer Research 53

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				Application Number 10/052,092
				Filing Date January 18, 2002
				First Named Inventor Suzanne Fuqua
				Art Unit N/A
				Examiner Name Not Yet Assigned
Sheet	3	of	4	Attorney Docket Number HO-P02102US2

		(24):5934 - 5939, December 15, 1993	
✓	CW	Keaveney, M., et al.; Evidence for a Previously Unidentified Upstream Exon in the Human Oestrogen Receptor Gene; <i>J. Mol. Endocr.</i> , Vol. 6:111 - 115, 1991	
✓	CX	Piva, R., et al.; Sequencing of an RNA Transcript of the Human Estrogen Receptor Gene: Evidence for a New Transcriptional Event; <i>J. Steroid Biochem. Molec. Biol.</i> , Vol. 46 (5), pages 531 - 538, 1993	
✓	CY	McDonnell, Donald P.; The Molecular Pharmacology of SERMs; <i>TEM</i> , Vol. 10 (8):301 - 311, 1999	
✓	CZ	Barkhem, Tomas, et al.; Differential Response of Estrogen Receptor a and Estrogen Receptor B to Partial Estrogen Agonists/Antagonists; <i>Molecular Pharmacology</i> , 54:105 - 112, 1998	
✓	CA1	Sun, Jun, et al.; Novel Ligands that Function as Selective Estrogens or Antiestrogens for Estrogen Receptor-a or Estrogen Receptor-B; <i>Endocrinology</i> , Vol. 140 (2):800 - 804, 1999	
✓	CB1	McDonnell, Donald P., et al.; Cellular Mechanisms Which Distinguish between Hormone- and Antihormone-Activated Estrogen Receptor; <i>Annals New York Academy of Sciences</i> , 761:121 - 137	
✓	CC1	Barkhem, Tomas, et al.; Characterization of the "Estrogenicity" of Tamoxifen and Raloxifene in HepG2 Cells: Regulation of Gene Expression from an ERE Controlled Reporter Vector Versus Regulation of the Endogenous SHBG and PS2 Genes; <i>J. Steroid Biochem. Molec. Biol.</i> , Vol. 62 (1), pages 53 - 64, 1997	
✓	CD1	Cowley, Shaun, M., et al.; Estrogen Receptors a and B Form Heterodimers on DNA; <i>The Journal of Biological Chemistry</i> , Vol. 272 (32), pages 19858 - 19862, August 8, 1997	
✓	CE1	Paige, Lisa A., et al.; Estrogen receptor (ER) modulators each induce distinct conformational changes in ER a and ER B; <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 96, pages 3999 - 4004, March 1999	
✓	CF1	Shiau, Andrew K., et al.; The Structural Basis of Estrogen Receptor/Coactivator Recognition and the Antagonism of This Interaction by Tamoxifen; <i>Cell</i> , Vol. 95, pages 927 - 937, December 28, 1998	
✓	CG1	Cowley, Shaun M., et al.; A comparison of transcriptional activation by ERa and ERB; <i>Journal of Steroid Biochemistry and Molecular Biology</i> , Vol. 69, pages 165 - 175, 1999	
✓	CH1	Tremblay, Gilles B., et al.; Cloning, Chromosomal Localization, and Functional Analysis of the Murine Estrogen Receptor B; <i>Molecular Endocrinology</i> 11:353 - 365, 1997	
✓	CI1	Witkowska, H. Ewa, et al.; Characterization of bacterially expressed rat estrogen receptor B ligand binding domain by mass spectrometry: Structural comparison with estrogen receptor a; <i>Steroids</i> 62:621 - 631, 1997	
✓	CJ1	McGuire, William L., et al.; Estrogen Receptor Variants In Clinical Breast Cancer; <i>Molecular Endocrinology</i> 5:1571 - 1577, 1991	
✓	CK1	van Agthoven, Ton, et al.; Differential Expression of Estrogen, Progesterone, and Epidermal Growth Factor Receptors in Normal, Benign, and Malignant Human Breast Tissues using Dual Staining Immunohistochemistry; <i>American Journal of Pathology</i> , Vol. 144 (6), pages 1238 - 1246, June 1994	
✓	CL1	Zhang, Zhi-Xia, et al.; An Estrogen Receptor Mutant with Strong Hormone-independent Activity from a Metastatic Breast Cancer; <i>Cancer Research</i> 57:1244 - 1249, April 1, 1997	
✓	CM1	Tremblay, Gilles B., et al.; Ligand-Independent Activation of the Estrogen Receptors a and B by Mutations of a Conserved Tyrosine Can Be Abolished by Antiestrogens; <i>Cancer Research</i> 58:877 - 881, March 1, 1998	
✓	CN1	Anandappa, Shanel Y., et al.; Variant estrogen Receptor a mRNAs In Human Breast Cancer Specimens; <i>Int. J. Cancer</i> 88, pages 209 - 216, 2000	
✓	CO1	Schuur, Eric R., et al.; Monoallelic Amplification of Estrogen Receptor-a Expression in Breast Cancer; <i>Cancer Research</i> 60, pages 2598 - 2601, May 15, 2000	

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				Art Unit	N/A
				Examiner Name	Not Yet Assigned
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CP1	Fasco, Michael J., et al.; Expression of an estrogen receptor alpha variant protein in cell lines and tumors; <i>Molecular and Cellular Endocrinology</i> 162, pages 167 - 180, 2000
CQ1	Rost, Natalia S., et al.; Immunochemical analyses of estrogen receptors in human breast tumors by a novel monoclonal estrogen receptor antibody (EVG F9); <i>Steroids</i> 65, pages 429 - 436, 2000
CR1	O'Connell, Peter, et al.; Analysis of Loss of Heterozygosity in 399 Premalignant Breast Lesions at 15 Genetic Loci; <i>Journal of the National Cancer Institute</i> , Vol. 90 (9), pages 697 - 703; May 6, 1998
CS1	Page, David L., et al.; Premalignant and Malignant Disease of the Breast: The Roles of the Pathologist; <i>Mod Pathol</i> 1998; 11(2):120 - 128
CT1	Page, David L.; The Woman at High Risk for Breast Cancer - Importance of Hyperplasia; <i>Special Problems in Breast Cancer Therapy</i> , Vol. 76 (2), pages 221 - 230, April 1996
CU1	Roger, Pascal, et al.; Dissociated Overexpression of Cathepsin D and Estrogen Receptor Alpha in Preinvasive Mammary Tumors; <i>Human Pathology</i> , Vol. 31 (5), pages 593 - 600, May 2000
CV1	Lishman, S. C., et al.; Atypical lobular hyperplasia and lobular carcinoma in situ: surgical and molecular pathology; <i>Histopathology</i> 1999, 35, 195 - 200
CW1	Page, David L., et al.; Evaluation and Management of High Risk and Premalignant Lesions of the Breast; <i>World J. Surg.</i> 18, 32 - 38, 1994
CX1	Page, David L., et al.; Anatomic Markers of Human Premalignancy and Risk of Breast Cancer; <i>Cancer</i> 66:1326 - 1335, 1990
CY1	Cardiff, R. D., et al.; Biology of Breast Preneoplasia; <i>Cancer</i> 39:2734 - 2746, 1977
CZ1	Stoll, B. A.; Premalignant Breast Lesions: Role for Biological Markers in Predicting Progression to Cancer; <i>European Journal of Cancer</i> , Vol. 35 (5), pages 693 - 697, 1999
CA2	Slentz-Kesler, Kimberly, et al.; Identification of the Human Mnk2 Gene (MKNK2) through Protein Interaction with Estrogen Receptor B; <i>Genomics</i> 69, 63 - 71, 2000
CB2	Dupont, William D., et al.; Risk Factors for Breast Cancer in Women with Proliferative Breast Disease; <i>N. Engl. J. Med.</i> 1985; 312:146 - 151
CC2	Lakhani, Sunil R.; The Transition from Hyperplasia to Invasive Carcinoma of the Breast; <i>Journal of Pathology</i> , 187:272 - 278, 1998

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